Appendix D

Table 1: Chlorhexidine Gluconate – Healthcare Personnel Handwash Studies

			S. marc	rescens						Neutral-	Statist.		Log Red (Versus I		
Formulation	Test Subjects	Baseline	47 1	Rub	Dry	Wash Vol.	Wash Time ¹	Rinse Time	Massage Time	ization 2,3	Signif. vs. baseline		Wash	No.	
	3	(log ₁₀ /hand)	Vol.	Time	Time						Dasenne	1	4	7	10
1994 TFM	-		ngunu kang sa pada dada dan dan pada dan dan sa kang sa pada dan dan sa pada dan dan sa pada dan dan sa pada d Maran dan sa pada dan sa pada dan sa pada dan d	-	**	_	*	-	**	-	-	2.0	-	-	3.0
			2.5												4 4 8
4% CHG Bartzokas et al. 1987	12	6.63	mL + 2.5 mL	45 sec	1 min	3 mL	30 sec	30 sec	1 min	Media	-	2.61 ±0.33 p<0.1	3.41 ±0.37 p<0.01	3.95 ±0.29 p<0.01	4.15 ±0.34 p<0.05
4% CHG Ciba 1990	12	7.07	2.5 mL + 2.5 mL	45 sec	1 min	3 mL	30 sec	30 sec	1 min	Media	NA	2.51 ±0.26	3.09 ± 0.13	3.37 ±0.18	3.92 ± 0.28
4% CHG Purdue Fred. 1986	9	NA	5 mL	To coat	1 min	5 mL	15 sec	NA	1 min	Media	NA	2.050	2.563	2.696	3.289
4% CHG Hibiclens Purdue Fred. 1986	9	NA	5 mL	To coat	1 min	5 mL	15 sec	NA	1 min	Media	NA	1.629	2.097	2.501	3.115
4% CHG Steris 1995	18	7.96	NA	NA	NA	5 mL	30 sec	NA	NA	Media	p ≤ 0.005	2.26	3.43	4.23	4.62
4% CHG Hibiclens Huntington 1994	6	6.356	6 mL	To coat	1 min	5 mL	30 sec	NA	1 min	Media	NA	NA	99.9921% Wash 5	NA	99.9949% Wash 5

Appendix D

Table 1: Chlorhexidine Gluconate – Healthcare Personnel Handwash Studies (continued)

			S. marce	escens						Neutral-	Statist.		Log Red (Versus)	luction Baseline)	
Formulation	Test Subjects	Baseline	Vol.	Rub	Dry	Wash Vol.	Wash Time ⁱ	Rinse Time	Massage Time	ization 2,3	Signif. vs.		Wasl	ı No.	
	-	(log ₁₀ /hand)	V 01.	Time	Time	1900 P					baseline	1	4	7	10
1994 TFM	-	**					•	-	-	•		2.0	-		3.0
4 % CHG Huntington 1994	6	6.356	6mL	To coat	1 min	5 mL	30 sec	NA	1 min	Media	NA	NA	99.982% Wash 5	NA	99.9997%
4% CHG Ballard, 1985	6	7.776	5 mL	NA	1 min	5 mL	15 sec	NA	1 min	Media	p<0.05	2.050	2.563	2.696	3.289
4% CHG Ballard, 1985	6	7.776	5 mL	NA	1 min	5 mL	15 sec	NA	1 min	Media	p<0.05	1.882	2.389	2.770	3.307
4% CHG (Hibiclens) Ballard, 1985	6	7.776	5 mL	NA	1 min	5 mL	15 sec	NA	1 min	Media	p<0.05	1.629	2.097	2.501	3.115
4% CHG Stiles & Sheena 1987	4	3.80	NA	NA	NA	NA	15 sec	15-20 sec	NA	Media	NA	2.52	NA	NA	NA
4% CHG Hibiclens Stuart Pharmaceutical 1986 ICI 1976	36	NA	NA	NA	NA	NA	15 sec	NA	NA	NA	NA	NA	3.85	NA	4,2649
4% CHG Hibiclens Stuart Pharmaceutical 1986 ICI 1976	36	NA	NA	NA	NA	NA	30 sec	NA	NA	NA	NA	NA	3.6928	NA	4.3192

Appendix D

Table 1: Chlorhexidine Gluconate – Healthcare Personnel Handwash Studies (continued)

			S. marce	escens						Neutral-	Statist.	·	Log Red (Versus		
Formulation	Test Subjects	Baseline		Rub	Dry	Wash Vol.	Wash Time ¹	Rinse Time	Massage Time	ization 2,3	Signif. vs.		Wasi	ı No.	
	,	(log ₁₀ /hand)	Vol.	Time	Time						baseline	1	4	7	10
1994 TFM	TT	-		••	**	_	**		_		•	2.0	••		3.0
4% CHG Ciba-Geigy 1990	12	NA	NA	NA	NA	3 mL	30 sec	NA	NA	NA	NA	~2.5	~3.2	~3.4	~3.9
4% CHG Ballard 1996	36	NA	NA	NA	1. min	5 mL	30 sec	NA.	1 min	NA	NA	NA	3.37 Wash 5	NA	3.84
4% CHG The Dial Corporation Undated	NA	8.46	NA	NA	NA	NA	NA	NA	NA	NA	NA	3.44	4.43	4.58	4.79
4% CHG (Hibiclens) The Dial Corporation Undated	NA	8.46	NA	NA	NA	NA	NA	NA	NA	NA	NA	2.78	3.63	3.89	4.22
4% CHG Gojo 1999	6	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	97.65%	99.2%	99.68%	99.92%
4% CHG Peterson et al. 1978	36	8.07	NA	NA	NA	5 mL	15 sec	NA	NA	NA	NA	NA	4.32 Wash 5	NA	5.49

Appendix D

Table 1: Chlorhexidine Gluconate – Healthcare Personnel Handwash Studies (continued)

			S. marce	escens						Neutral-	Statist.		Log Red (Versus E	luction Baseline)	
Formulation	Test Subjects	Baseline		Rub	Dry	Wash Vol.	Wash Time ⁱ	Rinse Time	Massage Time	ization 2,3	Signif.		Wash	No.	
	Bubjects	(log ₁₀ /hand)	Vol.	Time	Time					-	baseline	1	4	7	10
1994 TFM			en.	-		**	**	•	-	••	-	2.0	-	••	3.0
4% CHG Jampani et al. 1998	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	1.97	NA	NA	2.77
4% CHG Hibiclens Paulson 1994	36	6.8363	NA	NA	NA	5 mL	15 sec	NA	NA	NA	NA	NA	3.85 Wash 5	NA	4.2649
4% CHG Sheena & Stiles 1983 ⁴	s NA	2.90	NA	5 sec,	until dry	5 mL	15 sec	NA	NA	NA	NA	1.60	NA	NA	NA
4% CHG Sheena & Stile 1983 ⁴	s NA	2.81	NA	5 sec,	until dry	5 mL	15 sec + 15 sec	NA	NA	NA	NA	NA	1.81 Day 3, Wash 6	NA	NA
4% CHG Hibiclens Stuart Pharmaceutical 1986	16	NA	6 mL	NA	1 min	15 sec	NA	NA	NA	NA	NA	~3.2	~4.8 Wash 5	NA	~5.43
4% CHG The Dial Corporation Undated	NA	7.901 (left hand)	NA	NA	1 min	NA	NA	NA	NA	NA	p<0.01	NA	4.639 Wash 5	NA	4.080
4% CHG The Dial Corporation Undated	NA	7.969 (right hand)	NA	NA	1 min	NA	NA	NA	NA	NA	P<0.01	NA	4.494 Wash 5	NA	4.102

Appendix D

Table 1: Chlorhexidine Gluconate – Healthcare Personnel Handwash Studies (continued)

			S. marces	scens						Neutral-	Statist.	-	Log Rec	luction Baseline)	
Formulation	Test Subjects	Baseline		Rub	Dry	Wash Vol.	Wash Time ¹	Rinse Time	Massage Time	ization 2,3	Signif. vs.		Wasi	ı No.	
er en		(log ₁₀ /hand		Time	Time						baseline	1	4	7	10
1994 TFM	•	14	-	_	<u>an</u>	*	•		•		**	2.0	-	-	3.0
4% CHG Ciba-Geigy 1995	12	8.46	5 mL	45 sec	2 min	5 mL	15 sec	30 sec	NA	Glove (Wash 10)	NA	1.97	2.88 Wash 3	3.46	2.77
4% CHG Billhimer <i>et al.</i> 1998	11	7.3±0.20	50g ground beef	NA	1 min	NA	30 sec	NA	1 min	Glove	NA	3.3 ±0.89 ⁵	NA	NA	NA
4% CHG Stiles & Sheena 1985	NA	3.78	Contam - inated ground beef	5 sec	Until dry	5 mL	15 sec	15 sec	. NA	Glove	p<0.001	1.88	NA	NA	NA
4% CHG Stiles & Sheena 1985	NA	2.32	Contam - minated ground beef	5 sec	Until dry	5 mL	15 sec	15 sec	NA	Glove	p<0.01	0.28	NA	NA	NA
4% CHG Ciba 1995	12	8.32	5 mL	45 sec	2 min	5 mL	15 sec	30 sec	NA	Wash 1: Media Wash10: Glove	p<0.05	2.16	2.56	3.04	2.93
4% CHG Jampani et al. 1998	9*	NA	5 mL	45 sec	Air dry	5 mL	15 sec	30 sec	1 min	Wash 1: Media Wash10: Glove	P<0.05	1.92	NA	NA	2.84
4% CHG Ciba 1995	12	8.46	5 mL	45 sec	2 min	5 mL	15 sec	30 sec	NA	Wash 1: Media Wash10: Glove ³	p<0.05	1.97	2.88	3.46	2.77

Appendix D

Table 1: Chlorhexidine Gluconate – Healthcare Personnel Handwash Studies (continued)

			S. marces	cens			100 may 100 ma			Neutral-	Statist.		Log Re (Versus	duction Baseline)	
Formulation	Test Subjects	Baseline	**	Rub	Dry	Wash Vol.	Wash Time ¹	Rinse Time	Massage Time	ization 2,3	Signif. vs.		Was	h No.	
		(log ₁₀ /hand)	Vol.	Time	Time						baseline	1	4	7	10
1994 TFM	-	_	-		-	-	•	•				2.0			3.0
2% CHG Peterson 1978	36	8.07	NA	NA	NA	5 mL	15 sec	NA	NA	Media	NA	NA	NA	NA	5.49
2% CHG Stiles & Sheena 1987	4	3.81	NA	NA	NA	NA	15 sec	15-20 sec	NA	Media	NA	2.39	NA	NA	NA
2% CHG Gojo 1999	6	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	98.69%	99.59%	99.83%	99.95%
2% CHG Huntington 1992	NA	6.27	NA	NA	NA	NA	30 sec	NA	NA	NA	NA	NA	4.0 Wash 5	NA	4.0
2% CHG Ballard, 1998	NA	18.5	NA	NA	NA	5 mL	30 sec	NA	1 min	NA	NA	NA	99.99% Wash 5	NA	99.99%
2% CHG Stiles & Sheena 1985	NA	3.78	Contam - inated ground beef	5 sec	Until dry	5 mL	15 sec	15 sec	NA	Glove	p<0.001	1.48	NA	NA .	NA
2% CHG Stiles & Sheena 1985	NA	2.38	Contam - inated ground beef	5 sec	Until dry	5 mL	15 sec	15 sec	NA	Glove	p<0.01	0.10	NA	NA	ΝA
2.0% CHG Johnson 1998	1 1	8.40±0.25	5 mL	45 sec	Air dry	5 mL	15 sec	30 sec	1 min	Wash 1: Media Wash10: Glove	p<0.05	1.92 ±0.52	NA	NA	2.84 ±0.4

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Table 1: Chlorhexidine Gluconate – Healthcare Personnel Handwash Studies (continued)

			S. marce	scens						Neutral-	Statist.		Log Re	duction Baseline)	
		Vol.	Rub	Dry	Wash Vol.	Wash Time ¹	Rinse Time	Massage Time	ization 2,3	Signif. vs.		Was	sh No.		
	(log ₁₀ /hand)	7 01.	Time	Time						baseline	1	4	7	10	
1994 TFM	-		-	•	•	-	••		•	_	~	2.0	_	_	3.0
0.75% CHG Steris 1998	18	7.96	NA	NA	NA	5 mL	30 sec	NA	NA	Media	p≤0.005	2.07	2.98	3.92	4.22
CHG *Kaiser et al. 2000	18	NA	NA	NA	NA	NA	NA	NA	NA	Media	NA	2.0	NA	NA	3.3

- 1. The indication "15 sec + 15 sec" indicates that an initial wash time was used to wash the hands followed by a subsequent wash.
- 2. The term "Media" indicates that the neutralizers were incorporated into the dilution and plating media only.
- 3. The term "Glove" indicates that the neutralizers were incorporated into the sampling fluid in the glove.
- 4. E. coli inoculated on hands t hrough artificially contaminated ground beef.
- 5. Results were tested with water rinse.
- Results were with out water rinse.
 Log reduction values below the 1994 TFM criteria indicated by a shaded box and heavy outline.
- * Study not included in tally tables.

Appendix D

Table 2: Alcohol – Healthcare Personnel Handwash Studies

			S. marcesco	ens					Neutral	Statistical		Log Red (Versus B		
Formulation	Test	Baseline		Rub	Dry	Wash Vol. ¹	Wash Time	Massage Time	-ization	Signif. vs.		Wash	No.	
	Subjects	(log ₁₀ /hand)	Vol.	Time	Time	7 021	2		<i>~</i> 30	baseline	1	4	7	10
1994 TFM	-	-		***	~	-	-	-	-	_	2.0	-	•	3.0
60% Ethanol				45			NYA	1 min	Glove	NA	2.97	NA	NA	
Johnson 199 c	11	NA	5 mL	sec	2 min	5 mL	NA	1 min	Glove	IVA	2.91			2.74
60% ethanol Jones et al. 2000	10	8.76±0.28	1.5 mL + 1.5 mL + 1.5 mL	1 min	3 min	5 mL	45-75 sec	1 min	Wash 1: Media Wash 10: Glove	NA	2.97 ±0.36	NA	NA	2.74 ±0.69
60% ethanol Johnson Wax Undated	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	~1.8	NA	NA	NA
60% ethanol Johnson Wax Undated	NA	7.74	NA	NA	NA	NA	NA	NA	NA	NA	~2.5	~1.92 Wash 3	~2.0	~2.0
60% ethanol SDA/CTFA 1995	NA	NA	NA	NA	NA	NA	10 sec	NA	NA	NA	3.49- 3.53 Wash 2	NA	NA	NA
60% ethanol SDA/CTFA 1995	NA	NA	NA	NA	NA	5 mL	To dry	NA	NA	NA	2.91	3.53	3.94	3.93
60% ethanol SDA/CTFA 1995	NA	NA	NA	NA	NA	5 mL	To dry	NA	NA	NA	1.83	1.91 Wash 5	NA	2.38
60% ethanol SDA/CTFA 1995	NA	NA	NA	NA	NA	5 mL	To dry	NA	NA	NA	1.56	2.23 Wash 5	NA	2.64

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Table 2: Alcohol – Healthcare Personnel Handwash Studies

			S. marcesco	ens	,				Neutral	Statistical		Log Red (Versus B		
Formulation	Test Subjects	Baseline		Rub	Dry	Wash Vol. ¹	Wash Time	Massage Time	-ization	Signif. vs. baseline		Wash	No.	
	3	(log ₁₀ /hand)	Vol.	Time	Time					Dasenne	1	4	7	10
1994 TFM	-	•		-		-			•	-	2.0	-		3.0
62% alcohol Johnson & Johnson Medical 2000	12	NA ,	5 mL	45 sec	1 min	5 mL	Rub until dry	1 min	Glove Wash 10	NA	3.04	NA	NA	2.72
62% Ethanol Kimberly- Clark 1999	NA	4.09	1.5 mL + 1.5 mL + 15 mL	20 sec	1 min	5 mL + 2.5 mL	NA	1 min	NA	NA	3.83	2.84 Wash 3	2.68	2.86
62% Ethanol Kimberly- Clark 1999	NA	4.09	1.5 mL + 1.5mL + 1.5 mL	20sec	l min	5 mL+ 2.5 mL	ŅA	1 min	NA	NA	3.93	3.59 Wash 3	3.49	3.74
62% Ethanol Gojo 1999	5	NA	NA	NA	NA	NA	NA	NA	NA	NA	99.86%	99.74% Wash 3	98.45%	98.77%
62% Ethanol Paulson <i>et al</i> . 1999	25	3.99	5 mL	NA	l min	3 mL	NA	1 min	Media	NA	3.9 ±0.04	3.79 ±0.15	2.96 ±0.17	2.15 ±0.13
62% ethanol Dyer et al. 1998	17	NA	5 mL	45 sec	2 min	5 g	NA	1 min	Media	p0.05	~2.8	~2.8 Wash 3	~2.7	~2.4
62% ethanol Dyer et al. 1998	16	NA	5 mL	45 sec	2 min	5 g	NA	1 min	Media	p0.05	~2.0	~1.8 Wash 3	~1.5	~1.7

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			S. marceso	cens					Neutral	Statistical		Log Red (Versus B	uction laseline)	
Formulation	Subjects Baseline Vol Rub Di y	Baseline	Val	Rub	Dry	Wash Vol. ¹	Wash Time	Massage Time	-ization	Signif. vs. baseline		Wash	No.	
		Time					J	1	4	7	10			
1994 TFM		ad .	•	**	-	-			-	-	2.0	200	*	3.0
62% ethanol Paulson et al.	5	7.98±0.27	5 mL	NA	1 min	3 mL	Air dry 5 min	1 min	Media	NA	3.93 ±0.04	3.79 ±0.15 Wash 3	2.96 ±0.17	2.15 ±0.13

62% ethanol Paulson et al. 1999	5	7.98±0.27	5 mL	NA	1 min	3 mL	Air dry 5 min	1 min	Media	NA	3.93 ±0.04	3.79 ±0.15 Wash 3	2.96 ±0.17	2.15 ±0.13
62% ethanol Paulson 1994	. 5	7.98±0.27	5 mL	1 min	1 min	3 mL	Rub in, dry 5 min	1 min	Media	p<0.05	3.93 ±0.04	3.79 ±0.16	2.96 ±0.17	2.16 ±0.13
70% Ethanol Huntington 1995	6	8.10	5 mL	NA	2 min	3.5 mL	NA	1 min	Media	NA	2.59	2.07	1.96	1.97
70% ethanol Dyer et al. 1998	5	NA	5 mL	45 sec	2 min	5 g	NA	1 min	Media	p0.05	~2.8	~2.0 Wash 3	~1.5	~-1.3
70% ethanol Dyer et al. 1998	5	NA	5 mL	45 sec	2 min	5 g	NA	I min	Media	p0.05	~2.5	~2.5 Wash 3	~2.3	~2.0
70%IPA Aly & Maibach 1980	36	5.94	NA	NA	NA	NA	NA	NA	NA	p>0.20	NA	1.68 Wash 5	NA	1.6 Wash 10
80% ethanol SDA/CTFA 1995 a	NA	NA	NA	NA	NA	5 mL	To đry	NA	NA	NA	2.27	2.88 Wash 5	NA	1.94
Alcohol Kaiser et al. 2000	12	NA	NA	NA	NA	NA	NA	NA	Media	NA	2.0	NA	NA	2.3

Appendix D

Table 2: Alcohol – Healthcare Personnel Handwash Studies

		à.	S. marceso	ens					Neutral	Statistical		Log Red (Versus I	luction Baseline)	
Formulation	Subjects Ba	Baseline	Val	Rub	Dry	Wash Vol. ¹	Wash Time	Massage Time	-ization	Signif. vs. baseline		Wasi	No.	·
				Time					V.1.0 V.1.1.0	1	4	7	10	
1994 TFM	-	-	-		<u>-</u>		-	_	-	<u>-</u>	2.0		-	3.0

Ethanol (Alcare Foam) SDA/CTFA 1995 a 36 8.27±0.18 6 mL NA 60 sec 7 g	Rub until dry (~60 sec) Rub 1 min Media	NA NA 3.30 Wash 5	NA 3.46
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¹ The indication "5.0 mL + 2.5 mL" indicates that two additions of test material were used to reduce the loss t hrough the subject's fingers.

² The term "Media" indicates that the neutralizers were incorporated into the dilution and plating media only.

³ The term "Glove" indicates that the neutralizers were incorporated into the sampling fluid in the glove.

Log reduction values below the 1994 TFM criteria indicated by a shaded box

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Table 3: Povidone-Iodine – Healthcare Personnel Handwash Studies

			S. marceso	ens	•			·	Neutral	Statistical		Log Ret (Versus I		A & A A SHAWAN AND
Formulation	Test Subjects	Baseline	Vol.	Rub	Dry	Wash Vol. ¹	Wash Time	Massage Time	-ization 3,4	Signif. vs. baseline	Was		ı No.	
Subjects	(log ₁₀ /hand)	* 01.	Time	Time				and the second s		1	4	7	10	
1994 TFM	-		-		•	-	-		-	-	2.0	*		3.0

0.75% available I ₂ Sheena & Stiles 1983 ¹	NA	2.80	NA	5 sec	Until dry	5 mL	15 sec	NA	NA ·	NA	NA	1.79	NA	NA	NA .
0.75% available I ₂ Sheena & Stiles 1983 ¹	NA	2.56	NA	5 sec	Until dry	5 mL	15 sec	NA	NA	NA	NA	NA	1.56 ² Day 3, Wash 6	NA	NA
0.005% available I ₂ Sheena & Stiles 1983 ¹	NA	2.99	NA	5 sec	Until dry	5 mL	15 sec	NA	NA	NA	NA	1.38	NA	NA	NA
0.005% available I ₂ Sheena & Stiles 1983 ¹	NA	2.76	NA	5 sec	Until dry	5 mL	15 sec	NA	NA	NA	NA	NA	1.76 ² Day 3, Wash 6	NA	NA
25 ppm available I ₂ Sheena & Stiles 1983	NA	3.04	NA	5 sec	Until dry	5 mL	15 sec	NA	NA	NA	NA	1.34	NA	NA	NA
25ppm available I ₂ Sheena & Stiles 1983 ¹	NA	2.92	NA	5 sec	Until dry	5 mL	15 sec	NA .:	NA	NA	NA	NA	1.62 ² Day 3, Wash 6	NA	NA

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Table 3: Povidone-Iodine – Healthcare Personnel Handwash Studies (continued)

			S. marcesc	ens						Neutral	Statistical			duction Baseline)	
Formulation	Test Subjects	Baselii		Rub	Dry	Wash Vol.	Wash Time	Rinse Time	Massage Time	-ization	Signif. vs. baseline		Was	h No.	
		(log ₁₀ /har	nd) 7 01.	Time	Time				Per international designation of the second		Dusenne	1	4	7	10
1994 TFM	•	_	•	•	-	-	_	_	••			2.0	-	-	3.0
								,		,					T
7.5% PVP-I Peterson et al. 1978	36	7.83	NA	NA	NA	5 mL	15 sec	NA	NA ,	NA	NA	NA	3.78 Wash 5	NA	3.89 Wash 10
0.75% PVP-I Stiles & Sheena 1985	NA	3.82	Contaminated ground beef	3	Until dry	5 mL	15 sec	15 sec	NA	Glove	p<0.001	2.12	NA	NA	NA
0.5% PVP-I Stiles & Sheena 1985	NA	3.71	Contaminated ground beef	1	Until dry	5 mL	15 sec	15 sec	NA	Glove	p<0.001	1.71	NA	NA	NA
0.3% PVP-I Stiles & Sheena 1985	NA	3.80	Contaminate ground beef		Until dry	5 mL	15 sec	15 sec	NA	Glove	p<0.001	1.50	NA	NA	NA
0.1% PVP-I Stiles & Sheena 1985	NA	3.79	Contaminate ground beef	1	Until dry	5 mL	15 sec	15 sec	NA	Glove	p<0.001	1.79	NA	NA	NA
0.01% PVP-I Stiles & Sheena 1985	NA	2.11	Contaminated ground beef	3	Until dry	5 mL	15 sec	15 sec	NA	Glove	p<0.001	1.50	NA	NA	NA

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Table 3: Povidone-Iodine – Healthcare Personnel Handwash Studies (continued)

			S. marceso	ens						Neutral	Statistical		Log Re	duction Baseline)	
Formulation	Test Subjects	Baselin	e Vol.	Rub	Dry	Wash Vol.	Wash Time	Rinse Time	Massage Time	-ization 3,4	Signif. vs. baseline		Was	h No.	
		(log₁₀⁄han	d) Voi.	Time	Time							1	4	7	10
1994 TFM	**	-	-		-	-	•		-	-	-4	2.0	air .	•	3.0
								•		,					
0.75% PVP-I Stiles & Sheena 1985	NA	2.11	Contaminate ground beef	1	Until dry	5 mL	15 sec	15 sec	NA .	Glove	p<0.01	0.16	NA	NA	NA
0.5% PVP-I Stiles & Sheena 1985	NA	2.18	Contaminate ground beet	1	Until dry	5 mL	15 sec	15 sec	NA	Glove	p<0.01	0.13	NA	NA	NA
0.3% PVP-I Stiles & Sheena 1985	NA	2.34	Contaminate	1	Until dry	5 mL	15 sec	15 sec	NA	Glove	p<0.01	0.20	NA	NA	NA
0.1% PVP-I Stiles & Sheena 1985	NA	2.11	Contaminate ground bee		Until dry	5 mL	15 sec	15 sec	NA	Glove	p<0.01	+0.14	NA	NA	NA
0.01% PVP-I Stiles & Sheena 1985	NA	2.28	Contaminate ground bee	1	Until dry	5 mL	15 sec	15 sec	NA	Glove	p<0.01	0.02	NA	NA	NA
0.02% Available I ₂ Stiles & Sheena 1987	4	3.72	NA	NA	NA	NA	15 sec	15- 20 sec	NA	Media	NA	2.10	NA	NA	NA

Appendix D

Table 3: Povidone-Iodine – Healthcare Personnel Handwash Studies (continued)

			S. marceso	cens				_		Neutral	Statistical			duction Baseline)	
Formulation	Test Subjects	Baseline	Vol.	Rub	Dry	Wash Vol.	Wash Time	Rinse Time	Massage Time	-ization	Signif. vs. baseline		Was	sh No.	
	ŭ	(log ₁₀ /hand)		Time	Time						Dascine	1	4	7	10
1994 TFM	995.	-	-	-		-	***	-	-	-	**	2.0	200	***	3.0
						,						1		i -	
0.12% Available I ₂ Stiles & Sheena 1987	4	3.88	NA	NA	NA	NA	15 sec	15-20 sec	NA .	Media	NA	2.22	NA	NA	NA
0.75% Available I ₂ Stiles & Sheena 1987	4	3.81	NA	NA	NA	NA	15 sec	15-20 sec	NA	Media	NA	2.70	NA	NA	NA
I ₂ Kaiser <i>et al.</i> 2000	7	NA	NA	NA	NA	NA	NA	NA	NA.	Media	NA	3.5	NA	NA	4.0
7.5% PVP-I Rotter 1984	15	NA	NA	NA	NA	NA	1 min	NA	NA	Media	NA	3.2 ±0.5	NA	NA	NA

¹ E. coli inoculated onto hands through artificially contaminated ground beef.

² Two (2) consecutive washes

³The term "Media" indicates that the neutralizers were incorporated into the dilution and plating media only.

⁴The term "Glove" indicates that the neutralizers were incorporated into the sampling fluid in the glove.

Log reduction values below the 1994 TFM criteria indicated by a shaded box.

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Table 4: Chlorhexidine Gluconate – Surgical Scrub Studies

	Test	Resident Flora	Scrub	Scrub	Massage	Neutral	Regrowth		Log Reduction (Versus Baseline)
Formulation	Subjects	Baseline (log ₁₀ /hand)	Vol. ¹	Time ²	Time	-ization 3,4	Below Baseline	Scrub 1/ Day 1	Scrub 2/ Day 2	Scrub 11/ Day 5
1994 TFM	**	-	-			4	-	1.0	2.0	3.0
4% CHG Hibiclens Peterson et al. 1978	36	6.38 6.41	5 mL + 5 mL	3 min + 3 min	NA	Media	Below Baseline	3.64	3.89	4.11
4% CHG Huntington 1994	7	6.9263	5 mL + 5 mL	1 min + 3 min	1 min	Media	Below Baseline	2.5317	2.7833	2.8057
4% CHG Hibiclens Huntington 1994	. 6	6.8993	5 mL + 5 mL	3 min + 3 min	1 min	Media	Below Baseline	1.50	2.07	2.95
4% CHG Purdue Frederick 1985	12	5.0/hand	5 mL + 5 mL	3 min + 3 min	1 min	Plating Media Only	Below Baseline	2.80 p=0.001	3.17 p=0.001	4.18 p=0.001
4% CHG Hibiclens Purdue Frederick 1985	12	5.0/hand	5 mL + 5 mL	3 min + 3 min	1 min	Plating Media Only	Below Baseline	0.00 p=0.001	0.88 p=0.001	1.33 p=0.001
4% CHG Hibiclens Aly and Maibach 1988	13	>6.0	NA (Sponge /brush)	2 min	1 min	Media	Below Baseline	~1.5	~3.0	~4.0
4% CHG Loeb <i>et al.</i> 1997	15	3.47 (1.4-5.05)	15 mL	5 min w/scrub brush	1 min	Media	Below Baseline at 45 min	2.98 (-0.07- 4.15)	NA	NA

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Table 4: Chlorhexidine Gluconate – Surgical Scrub Studies

	Test	Resident Flora	Scrub	Serub	Massage	Neutral- ization	Regrowth Below		Log Reductio (Versus Baseline	
Formulation	Subjects	Baseline (log ₁₀ /hand)	Vol. ¹	Time ²	Time	3,4	Below Baseline	Scrub 1/ Day 1	Scrub 2/ Day 2	Scrub 11/ Day 5
1994 TFM	-	-	•		b-	-	-	1.0	2.0	3.0
4% CHG	1.5	3.45	15 mL	5 min	1 min	Media	Below Baseline at	3.09	NA	NA
Loeb et al. 1997	15	(1.85-4.72)	13 1111	brush	A 111111	IVICUIA	45 min (-0.50-3.88)	1.80-3.95		
4% CHG Mulberry et al. 2000	24	6.4	5 mL+ 5 mL	3 min+ 3 min	1 min	Media	Below Baseline	1.8	2.6	3.7
4% CHG Mulberry et al. 2000	19	6.0	5 mL+ 5 mL	3 min+ 3 min	1 min	Media	Below Baseline	1.6	2.4	3.6
4% CHG Brush Paulson 1994	6	6.57	NA	2 min	1 min	Media	Below Baseline	3.52	2.94	4.67
4% CHG Johnson & Johnson Medical 2000	11	NA	5 mL + 5 mL	6 min + 6 min	1 min	Media	Below Baseline	2.32	2.62	3.17
4% CHG Johnson & Johnson Medical 2000	12	NA	5 mL + 5 mL	3 min + 3 min	1 min	Media	Below Baseline	2.37	3.30	3.12
4% CHG Johnson & Johnson Medical 2000	9	NA	5 mL + 5 mL	6 min + 6 min	1 min	Media	Below Baseline	2.10	2.60	3.08

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Table 4: Chlorhexidine Gluconate – Surgical Scrub Studies

	Test	Resident Flora	Scrub	Scrub	Massage	Neutral- ization	Regrowth Below		Log Reductio (Versus Baseline	
Formulation	Subjects	Baseline (log ₁₀ /hand)	Vol. ¹	Time ²	Time	3,4	Below Baseline	Scrub 1/ Day 1	Scrub 2/ Day 2	Scrub 11/ Day 5
1994 TFM		-	-		179.	-	•	1.0	2.0	3.0
4% CHG Johnson & Johnson Medical 2000	12	NA	5 mL + 5 mL	3 min + 3 min	1 min	Media .	Below Baseline	2.28	3.15	3.59
4% CHG Rotter 1984	16	NA	NA	1 min	NA	Media	NA	3.0 ±0.5	NA	NA
4% CHG Ciba-Geigy 1990	15	NA	5 g	30 sec	NA	NA	Below Baseline at 3 hr	~0.87	NA	~0.92
4% CHG (Hibiclens) Johnson Wax Undated	NA	NA	Per label directions	Per label directions	NA	NA	Below Baseline	~0.9	~1.6	~2.4
4% CHG The Dial Corporation Undated	NA	6.40	Per label directions	3 min+ 3 min	NA	NA	Below Baseline	3.13	3.80	4.64
4% CHG The Dial Corporation Undated	NA	NA	Per label directions	Per label directions	NA	NA	Below Baseline	2.30	3.75	4.70

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Table 4: Chlorhexidine Gluconate – Surgical Scrub Studies

	Test	Resident Flora	Scrub	Scrub	Massage	Neutral- ization	Regrowth Below		Log Reductio (Versus Baseline	
Formulation	Subjects	Baseline (log ₁₀ /hand)	Vol. ¹	Time ²	Time	3,4	Below Baseline	Scrub 1/ Day 1	Scrub 2/ Day 2	Scrub 11/ Day 5
1994 TFM		e e	-		-	-	_	1.0	2.0	3.0
4% CHG (Hibiclens) The Dial Corporation Undated	NA	NA	NA	NA	NA	NA ·	Below Baseline at 2 hr	3.32	NA	NA
4% CHG FOAM **Ballard, 1996	18	NA	5 mL + 5 mL	3 min + 3 min	1 min	NA	Below Baseline	1.31	1.76	2.79
4% CHG FOAM **Ballard, 1996	18	NA	5 mL + 5 mL	3 min + 3 min	1 min	NA	Below Baseline	2.06	2.65	3.57
4% CHG Hibiclens **Ballard, 1996	18	NA	5 mL + 5 mL	3 min + 3 min	1 min	NA	Below Baseline at 2 hr	3,32	NA	NA
4% CHG FOAM **Ballard, 1996	18	NA	5 mL + 5 mL	3 min + 3 min	1 min	NA	Below Baseline at 2 hr	3.63	NA	NA
4% CHG Jampani <i>et al</i> . 1998	NA	NA	NA	NA	NA	NA	Below Baseline	2.37	3.3	3.12
4% CHG Hibiclens Rosenberg et al. 1976	30	6.3707	5 mL+ 5 mL	6 min	NA	NA	Below Baseline	1.9398	2.5371	2.6885

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Table 4: Chlorhexidine Gluconate – Surgical Scrub Studies

	Test	Resident Flora	Scrub	Scrub	Massage	Neutral- ization	Regrowth	,	Log Reductio (Versus Baseline	n)
Formulation	Subjects	Baseline (log ₁₀ /hand)	Vol. ¹	Time ²	Time	3,4	Below Baseline	Scrub 1/ Day 1	Scrub 2/ Day 2	Scrub 11/ Day 5
1994 TFM		•			•	**	**	1.0	2.0	3.0
4% CHG Hibiclens Stuart Pharmaceuticals 1986	-10	NA	NA	6 min	NA	NA ·	Below Baseline	1.9398	2.5371	2.6885
4% CHG Hibiclens Stuart Pharmaceuticals 1986	42	6.3963	NA Sponge brush	3 min+ 3 min	NA	NA	Below Baseline	1.7363	2.206	3.0603
4% CHG (Hibiclens) The Dial Corporation Undated	NA	NA	Per label directions	Per label directions	NA	NA	Below Baseline	1.95	2.80	4.25
4% CHG The Dial Corporation Undated	NA	NA ·	NA	NA	NA	NA	Below Baseline at 2 hr	3.63	NA	NA

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Table 4: Chlorhexidine Gluconate – Surgical Scrub Studies

	Test	Resident Flora	Scrub	Scrub	Massage	Neutral- ization	Regrowth Below	,	Log Reductio (Versus Baseline	
Formulation	Subjects	Baseline (log ₁₀ /hand)	Vol. ¹	Time ²	Time	3,4	Baseline	Scrub 1/ Day 1	Scrub 2/ Day 2	Scrub 11/ Day 5
1994 TFM	-	-		•	-	-	-	1.0	2.0	3.0
4% CHG Hibiclens Aly and Maibach 1983	13	>6.0	NA (Sponge/ brush)	3 min + 3 min	1 min	Glove .	Below Baseline at 2 hr	1.8887	2.9744	3.7860
4% CHG Babb <i>et al</i> . 1991	27	NA	5 mL + 5 mL	3 min	NA	Glove	Below Baseline at 3 hr	0.35	NA	NA
4% CHG Babb <i>et al</i> . 1991	27	NA	5 mL + 5 mL	3 min	NA	Glove	Below Baseline at 3 hr	0.48	NA	NA
4% CHG Babb <i>et al</i> . 1991	27	NA	5 mL + 5 mL	3 min	NA	Glove	Below Baseline at 3 hr	1.01	NA	NA
4% CHG Larson <i>et al.</i> 1990	12	5.80±0.58	5 mL+ 5 mL	5 min	1 min	Glove	Below Baseline	0.86	NA	1.56
4% CHG Lowbury <i>et al.</i> 1974	NA	NA	5 mL+ 5 mL	~2 min	NA	Glove	Below Baseline at 3 hr	87.1% ±3.5	NA	NA
4% CHG Larson & Bobo 1992	12	5.32±0.49	5 mL	15 sec	NA	Glove	NA	0.57	NA	NA
4% CHG Rotter 1984	16	NA	NA	1 min	NA	Glove	NA	4.8 ±0.5	NA	NA

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Table 4: Chlorhexidine Gluconate – Surgical Scrub Studies

Formulation	Test	Resident Flora	Scrub	Scrub	Massage	Neutral- ization	Regrowth		Log Reduction (Versus Baseline	
rormulation	Subjects	Baseline (log ₁₀ /hand)	Vol. ¹	Time ²	Time	3,4	Below Baseline	Scrub 1/ Day 1	(Versus Baselin Scrub 2/ Day 2 2.0 NA NA NA 0.21*	Scrub 11/ Day 5
1994 TFM	· •	-	 	-	**	-		1.0	2.0	3.0
4% CHG Larson <i>et al</i> . 2001	25	4.41 – 5.15	Sponge	3 min + 3 min	1 min	Glove	NA	0.81	NA	0.73
4% CHG Reverdy et al. 1984	10	6.47±0.39	5 mL + 5 mL	1 min + Rub until dry	5 min	Glove	NA	0.80 (Aerobic bacteria)	NA	NA
4% CHG Morrison et al. 1986	10	4.5-4.6 ±0.10-0.12	2 mL	10 sec (Wash 4, I min)	5 sec	Glove	NA .	0.19	0.21 * Week 2/ Wash 2	0.25* Week 3/ Wash
4% CHG Hibiclens Larson <i>et al</i> . 1986	10	7.02	5 mL	15 sec	1 min	Glove	NA	1.09	NA	NA
4% CHG Butz <i>et al.</i> 1990b	12	5.760±0.726	3 mL	15 sec	1 min	Glove	NA.	-0.127± 0.470	NA	NA
4% CHG Larson <i>et al</i> . 1987	10	6.40-6.93	1 mL	15 sec	3 min	Glove	NA	0.29	NA	NA

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Table 4: Chlorhexidine Gluconate – Surgical Scrub Studies

Formulation	Test	Resident Flora	Scrub	Scrub	Massage	Neutral- ization	Regrowth Below		Log Reduction (Versus Baseline)	
Formulation	Subjects	Baseline (log ₁₀ /hand)	Vol. ¹	Time ²	Time	3,4	Baseline	Serub 1/ Day 1	Scrub 2/ Day 2	Scrub 11/ Day 5
1994 TFM		-	-	-		-	-	1.0	2.0	3.0
and the second s				I						
4% CHG Babb <i>et al.</i> 1991	27	NA	5 mL + 5 mL	3 min	NA	Glove .	Below Baseline at 3 hr	0.84	NA	NA
4% CHG Cremieux et al. 1989	35	Day 1: 6.51±0.58 Day 2: 5.44±0.46 Day 5: 5.06±0.57	5 mL + 5 mL	1 min + 3 min	5 min	Glove	NA	0.76±0.53 p=0.896	1.75 <u>+</u> 0.48	2.39±0.58 p=0.002
4% CHG Faogali <i>et al.</i> 1995	33	NA	5 mL + 5 mL	3 min + 3 min	1 min	Glove	Below Baseline at 3 hr	1.06±0.58 p<0.05	NA	1.40±1.11 p<0.05
4% CHG Bendig 1990	20	NA	5 mL+ 5 mL	1 min+ 2 min	NA	Glove	Below Baseline at 3 hr	1.55	NA	NA
4% CHG Larson <i>et al.</i> 1987	10	6.40-6.93	3 mL	15 sec	3 min	Glove	NA	0.51	NA	NA
4% CHG Larson <i>et al</i> . 1987	10	6.63	NA	15 sec	15 sec	Glove	NA	1.13	NA	NA
4% CHG Hobson <i>et al.</i> 1998	18	5.99-6.16	NA	6 min	NA	Glove	Below Baseline	1.68± 0.85	1.99± 1.69	3.43± 1.26
4% CHG Larson <i>et al</i> . 1987	10	6.20	NA	15 sec	15 sec	Glove	NA	0.71	NA	NA
4% CHG Stiles & Sheena 1985	NA	2.08	5 mL	15 sec	NA	Glove	NA	0.38	NA	NA

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Table 4: Chlorhexidine Gluconate – Surgical Scrub Studies

	Test	Resident Flora	Scrub	Scrub	Massage	Neutral- ization	Regrowth Below		Log Reductio (Versus Baseline	n)
Formulation	Subjects	Baseline (log ₁₀ /hand)	Vol. ¹	Time ²	Time	3,4	Below Baseline	Scrub 1/ Day 1	Scrub 2/ Day 2	Scrub 11/ Day 5
1994 TFM	-	-	*	_	-	-	•	1.0	2.0	3.0
4% CHG Larson & Laughon 1987	10	5.94 ± 0.51	4 mL	15 sec	1 min	Glove	NA	0.34	NA	NA
4% CHG Hibiclens Larson & Laughon 1987	10	6.28 ± 0.60	4 mL	15 sec	1 min	Glove	NA	0.88	NA	NA
4% CHG Larson & Laughon 1987	10	5.88 ± 0.49	NA	15 sec	1 min	Glove	NA	0.20	NA	NA
4% CHG Hibiclens Pereira et al. 1990	34	5.154-5.404	2 mL+ 2 mL+ 2 mL+ 2 mL	Wash 1, 5 min Wash 2 etc, 3 min	1 min	Glove	Below Baseline at 2 hr	1.407	NA	NA
4% CHG Hibiclens Pereira et al. 1990	34	5.227-5.408	5 mL+ 5 mL	Wash 1, 3 min Wash 2 etc, 30 sec	1 min	Glove	Below Baseline at 2 hr	1.548	NA	NA

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Table 4: Chlorhexidine Gluconate – Surgical Scrub Studies

	Test	Resident Flora	Scrub	Scrub	Massage	Neutral-	Regrowth		Log Reduction (Versus Baseline)	n
Formulation	Subjects	Baseline (log ₁₀ /hand)	Vol. ¹	Time ²	Time	ization 3,4	Below Baseline	Scrub 1/ Day 1	Scrub 2/ Day 2	Scrub 11/ Day 5
1994 TFM	en	-	_			-	en e	1.0	2.0	3.0
	1004									
2% CHG Huntington 1992; Huntington 1994b	7	6.44	5 mL + 5 mL	3 min + 3 min	1 min	Media .	Below Baseline	1.79	1.94	4.13
2%CHG sol'n. Paulson 1994	6	6.57	10 mL	2 min	1 min	Media	Below Baseline	0.79	2.33	3.42
2%CHG Larson <i>et al.</i> 1989 ⁵	10	6.16±0.71	3 mL	30 sec	1 min	Glove	NA	0.28	NA	NA
2%CHG Larson <i>et al.</i> 1989 ⁶	10	6.01±0.52	3 mL	30 sec	1 min	Glove	NA	0.28	NA	NA
2%CHG Jones <i>et al</i> . 2000	36	6.45±0.27	5 mL+ 5 mL	6 min	1 min	Glove	Below Baseline	~1.4	~1.8	~2.8
2% CHG Stiles & Sheena 1985	NA	2.00	5 mL	15 sec	NA	Glove	NA	0.30	NA	NA
2% CHG Larson & Laughon 1987	10	5.67 <u>+</u> 0.54	4 mL	15-sec	1 min	Glove	NA	0.07	NA	NA

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Table 4: Chlorhexidine Gluconate – Surgical Scrub Studies

	Test	Resident Flora	Scrub	Scrub	Massage	Neutral- ization	Regrowth Below	`	Log Reductio (Versus Baseline	
Formulation	Subjects	Baseline (log ₁₀ /hand)	Vol. ¹	Time ²	Time	3,4	Baseline	Scrub 1/ Day 1	Scrub 2/ Day 2	Scrub 11/ Day 5
1994 TFM	•	**	44	-	:			1.0	2.0	3.0
2% CHG FOAM ** Ballard 1998	NA	6.44	5 mL + 5 mL	3 min + 3 min	1 min	NA	Below Baseline	1.79	1.94	4.13
2% CHG Johnson Wax Undated	NA	NA	Per label direc- tions	Per label direc- tions	NA	NA	Below Baseline	~1.9	~2.9	~3.9
1.5% CHG *Reverdy <i>et al</i> . 1984	10	6.17±0.46	5 mL+ 5 mL	1 min+ Rub until dry	5 min	Glove	NA	0.67 (Aerobic bacteria)	NA	NA
0.5% CHG Lowbury <i>et al.</i> 1974	6	NA	5 mL+ 5 mL	~2 min	NA	Glove	NA	65.1% ±8.66	91.8%* ±2.37 Wash 6, Day 2	NA
0.5% CHG Lowbury <i>et al.</i> 1974	NA	NA	gauze applica- tion	~2 min	NA	Glove	Below Baseline at 3 hr	60.7% ±6.0	NA	NA
0.5% CHG Stuart Pharmaceuticals 1986 Rosenberg et al. 1976	10	NA	NA	6 min	NA	NA	Below Baseline	1.5003	1.5721	1.8692

Appendix D Table 4: Chlorhexidine Gluconate – Surgical Scrub Studies

- The indication "5 mL + 5 mL" indicates that an initial volume of test material was used to scrub the hands for the time indicated followed by a subsequent addition of test material and scrub.
- 2 The indication "5 min + 5 min" indicates that an initial scrub time was used to scrub the hands followed by a subsequent additional scrub.
- 3 The term "Media" indicates that the neutralizers were incorporated into the dilution and plating media only.
- 4 The term "Glove" indicates that the neutralizers were incorporated into the sampling fluid in the glove.
- 5 Group washed 6x/day for 5 days
- 6 Group washed 18x/day for 5 days
- * Data not included in the tally tables.
- ** Additional information provided by sponsor.

 Log reduction values below 1994 TFM criteria indicated by a shaded box and heavy outline.

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Table 5: Alcohol – Surgical Scrub Studies

	Test	Resident Flora	Scrub	Serub	Massage	Neutral	Regrowth		Log Reductio	n)
Formulation	Subjects	Baseline (log ₁₀ /hand)	Vol. ¹	Time ²	Time	-ization 3,4	Below Baseline	Scrub 1/ Day 1	Scrub 2/ Day 2	Scrub 11/ Day 5
1994 TFM	•	-	-	-	**		*	1.0	2.0	3.0
Alcohol impregnated Brush *Paulson 1994	б	6.57	NA	2 min	1 min	Media	Above Baseline at 6 hr	0.20	0.86	0.49
60% n-Propanol *Ciba-Geigy 1981	15	5.16±0.15	3 mL+ 3 mL+ 3 mL+ 3 mL+ 3 mL	5 min	1 min	Glove	Below Baseline at 3 hr	2.32	NA	NA
Alcohol (Vestal Foam) *SDA/CTFA 1996	30	6.18-6.60	5g+ 2.5g	1-1.5 min + 0.5 min	1 min	Media	NA	1.87	2.24	2.36
Alcohol based (Triseptin) *Healthpoint Medical 1996	12	At least 5.18	"palm- ful"	1.5 min rinse, + 1.5 min	NA	NA	Below Baseline	2.9	3.4	4.78
Alcohol based (Triseptin) *Healthpoint Medical 1996	12	At least 5.18	"palm- ful" w/brush	1.5 min rinse, + 1.5 min	NA	NA	Below Baseline	~2.7	~3	~4.5
Alcohol based (Triseptin) *Healthpoint Medical 1996	12	At least 5.18	"palm- ful" w/ sponge	1.5 min rinse, + 1.5 min	NA	NA	Below Baseline	~2.3	~2.9	~4.3
30% ethanol wipe *Butz et al. 1990	12	5.75±0.425	NA	15 sec	1 min	Glove	NA	-0.008	NA	NA

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Table 5: Alcohol – Surgical Scrub Studies

	Test	Resident Flora	Serub	Scrub	Massage	Neutral	Regrowth		Log Reduction (Versus Baseline	
Formulation	Subjects	Baseline (log _{to} /hand)	Vol. ¹	Time ²	Time	-ization 3,4	Below Baseline	Scrub 1/ Day 1	Scrub 2/ Day 2	Scrub 11/ Day 5
1994 TFM	-	•	.	•	•	-		1.0	2.0	3.0
60% ethanol Jones <i>et al</i> . 2000	36	6.45±0.27	5 mL+ 5 mL	45-75 sec + 45-75 sec	1 min	Wash 1: Media Wash 11: Glove	Below Baseline	~2.1	~2.4	~2.5
60% IPA Morrison et al. 1986	14	4.5-4.6 ±0.10-0.12	1 mL	10-15 sec until dry	5 sec	Glove '	NA	1.4	0.5* Week 2/ Wash 2	0.5* Week 3/ Wash 3
60% IPA Larson et al. 1986	10	6.25	2 mL	15 sec	3 min	Glove	NA	1.34	NA	NA
60% IPA Larson <i>et al</i> . 1987	10	6.40-6.93	1 mL	15 sec dry 45 sec	3 min	Glove	NA ′	1.47	NA	NA
60% IPA Larson <i>et al</i> . 1987	10	6.40-6.93	3 mL	15 sec dry 45 sec	3 min	Glove	NA	1.74	NA	NA
60% IPA Larson <i>et al</i> . 1987	10	6.80	NA	15 sec	15 sec	Glove	NA	1.52	NA	NA
60% IPA Larson <i>et al.</i> 1987	10	7.06	NA	15 sec	3 min	Glove	NA	1.50	NA	NA

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Table 5: Alcohol – Surgical Scrub Studies

Formulation	Test	Resident Flora	Scrub	Scrub	Massage	Neutral	Regrowth		Log Reduction (Versus Baseline	
X Of Hithatton	Subjects	Baseline (log _{to} /hand)	Vol. ¹	Time ²	Time	-ization 3,4	Below Baseline	Scrub 1/ Day 1	Scrub 2/ Day 2	Scrub 11/ Day 5
1994 TFM	*		_	-	-	<u>-</u>		1.0	2.0	3.0
70% IPA SDA/CTFA 1995	NA	NA	NA	5 min	NA	NA	NA	2.54	NA	NA
70% IPA SDA/CTFA 1995	NA	NA	NA	5 min	NA	NA	NA	3.17	NA	NA
70% IPA SDA/CTFA 1995	NA	NA	NA	5 min	NA	NA	NA	2.99	NA	NA
70% IPA SDA/CTFA 1995	NA	NA	NA	5 min	NA	NA	NA	2.50	NA	NA
70% IPA Larson & Bobo 1992	12 ,	5.91±0.58	5 mL	15 sec	NA .	Glove	NA	0.87	NA	NA
70% IPA Larson <i>et al</i> . 1986	10	7.09	2 mL	15 sec	3 min	Glove	NA	1.2	NA	NA
70% IPA Reverdy <i>et al</i> . 1984	10	6.57±0.49	5 mL+ 5 mL	1 min+ Rub until dry	5 min	Glove	NA	1.66 (Aerobic bacteria)	NA	NA

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Table 5: Alcohol – Surgical Scrub Studies

	Test	Resident Flora	Scrub	Scrub	Massage	Neutral	Regrowth		Log Reductio (Versus Baseline	
Formulation	Subjects	Baseline (log ₁₀ /hand)	Vol. ¹	Time ²	Time	-ization	Below Baseline	Scrub 1/ Day 1	Scrub 2/ Day 2	Scrub 11/ Day 5
1994 TFM			**			•		1.0	2.0	3.0
70% IPA Hough, Hoseason & Company, Ltd. Undated	10	NA	NA	NA	NA .	Glove	Below Baseline at 3 hr	2.3299	NA	NA
70% IPA Lowbury <i>et al.</i> 1974	NA	NA	gauze applica- tion	~2 min	NA	Glove '	Below Baseline at 3 hr	84.8% ±3.1	NA	NA
70% IPA Babb <i>et al</i> . 1991	24	NA	5 mL + 5 mL	30 sec	NA	Glove	Below Baseline at 3 hr	1.50	NA	NA
70% IPA Babb <i>et al</i> . 1991	24	NA	5 mL + 5 mL	3 min	NA	Glove	Below Baseline at 3 hr	1.65	NA	NA
70% IPA Morrison <i>et al.</i> 1986	10	4.5-4.6 ±0.10-0.12	2 mL	10 sec wash 4, 1 min	5 sec	Glove	NA	0.05	0.17* Week 2/ Wash 2	0.07* Week 3/ Wash 3
70% IPA Morrison <i>et al.</i> 1986	14	4.5-4.6 ±0.10-0.12	1 mL	10-15 sec until dry	5 sec	Glove	NA	-0.5	0.3* Week 2/ Wash 2	0.0* Week 3/ Wash 3

Appendix D Table 5: Alcohol – Surgical Scrub Studies

- 1 "5 mL + 5 mL" indicates that the initial volume indicated of test material was used for the time indicated followed by a subsequent addition of test material and scrub.
- 2 The indication "5 min + 5 min" indicates that an initial scrub time was used to scrub the hands followed by a subsequent scrub.
- 3 The term "Media" indicates that the neutralizers were incorporated into the dilution and plating media only.
- 4 The term "Glove" indicates that the neutralizers were incorporated into the sampling fluid in the glove.
- 5 Range of values shown are for three application methods.
- * Data not included in the tally tables.
- Log reduction values below the 1994 TFM criteria indicated by a shaded box and heavy outline.

Appendix D

Table 6: I	Povidone-Iodine -	- Surgical	Scrub Studies
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Formulation	Test	Resident Flora Baseline	Scrub	Scrub	Massage	Neutral -ization	Regrowth Below		Log Reductio (Versus Baseline)
	Subjects	(log ₁₀ /hand)	Vol. ¹	Time ²	Time	3,4	Baseline	Scrub 1/ Day 1	Serub 2/ Day 2	Scrub 11/ Day 5
1994 TFM	-	·	*	•	••	•		1.0	2.0	3.0
7.5% PVP-I Betadine Huntington 1995	14	5.544	5 mL + 5 mL	5 min + 5 min	NA	Media	Below Baseline	1.97	1,95	1.82
7.5% PVP-I Huntington 1995	13	5.502	NA	3 min + 3 min	NA	Media	Below Baseline	2.054	2.061	3.514
7.5% PVP-I Huntington 1995	5	6.877	NA	3 min + 3 min	NA	Media	Below Baseline	1.76	2.273	1.942
7.5% PVP-I Betadine Peterson <i>et al</i> . 1978	36	6.37	5 mL + 5 mL	3 min + 3 min	NA	Media	Below Baseline	2.24	2.46	2.76
7.5% PVP-I Aly and Maibach 1988	12	>6.0	NA (Sponge/ brush)	2 min	1 min	Media	Above Baseline at 6 hr	≅1.0	≅1.0	≅1.0
7.5% PVP-I Johnson & Johnson Medical 2000	11	NA	5 mL + 5 mL	6 min + 6 min	1 min	Media	Above Baseline	1.46	1.57	1.54
7.5% PVP-I Betadine Kubista and Lusskin 1979	25	NA	5 mL + 5 mL	5 min + 5 min	NA	NA	Below Baseline	1.0	NA	*1.0 Day 4
7.5% PVP-I Harrison <i>et al</i> . 1999	12	NA	NA	NA	NA	NA	Below Baseline	~1.4	~1.5	~1.5

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Table 6: Povidone-Iodine – Surgical Scrub Studies (continued)

Formulation	Test	Resident Flora Baseline	Scrub	Scrub	Massage	Neutral- ization	Regrowth Below		Log Reduction (Versus Baseline	
	Subjects	(log ₁₀ /hand)	Vol.1	Time ²	Time	3,4	Baseline	Scrub 1/ Day 1	Scrub 2/ Day 2	Scrub 11/ Day 5
1994 TFM	-	-	-	-	*	-	se	1.0	2.0	3.0
					1					
7.5% PVP-I (Betadine) Healthpoint, Medical 1996	12	At least 5,18	Per label instruc- tions	Per label instruc- tions	NA	NA	Above Baseline	1.19	1.28	1.27
7.5% PVP-I FOAM Huntington 1992	NA	NA	NA	5 min + 5 min	NA	NA	NA	99.85%	99.5%	99.31%
7.5% PVP-I Peterson <i>et al.</i> 1978	36	6.37	10 mL	6 min	NA	NA	Below Baseline	2.24	2.46	2.76
7.5% PVP-I Foam Ballard 1984	17	Range: 5-7 log ₁₀	4 mL with a	3 min	1 min	None	Not done	1.620	1.866 Day 3/ Scrub 3	1.956 Scrub 5
			Brush					Subject Crerepresent a	ossover and Re	peat. Values study weeks.
7.5% PVP-I Larson & Bobo 1992	12	5.52±0.46	5 mL	15 sec	NA	Glove	NA	0.21	NA	NA

Appendix D

Table 6: Povidone-Iodine – Surgical Scrub Studies (continued)

Formulation	Test Subjects	Resident Flora Baseline (log ₁₀ /hand)	Scrub Vol. ¹	Scrub Time ²	Massage Time	Neutral- ization 3,4	Regrowth Below Baseline	Log Reduction (Versus Baseline)		
								Scrub 1/ Day 1	Scrub 2/ Day 2	Scrub 11/ Day 5
1994 TFM		-	444	**			-	1.0	2.0	3.0
7.5% PVP-I Betadine Pereira <i>et al.</i> 1990	34	5.282-5.491	2 mL+ 2 mL+ 2 mL+ 2 mL	Wash 1, 5 min Wash 2 etc., 3 min	1 min	Glove .	Below Baseline at 2 hr	1.158	NA	NA
7.5% PVP-I Betadine Pereira <i>et al</i> . 1990	34	5.198-5.300	5 mL+ 5 mL	Wash 1, 3 min Wash 2 etc., 30 sec	1 min	Glove	Below Baseline at 2 hr	0.987	NA	NA
7.5% PVP-I Babb <i>et al</i> . 1991	24	NA	5 mL + 5 mL	3 min	NA	Glove	Below Baseline	0.80	NA	NA
7.5% PVP-I (Betadine) Larson <i>et al</i> . 1990	12	6.18±0.39	5 mL+ 5 mL	5 min	1 min	Glove	Below Baseline	1.08	NA	1.57
4% PVP-I *Reverdy <i>et al</i> . 1984	10	6.33±0.24	5 mL+ 5 mL	1 min + 3 min	5 min	Glove	NA	1.28 (Aerobic bacteria)	NA	NA

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Table 6: Povidone-Iodine – Surgical Scrub Studies (continued)

Formulation	Test	Resident Flora	Scrub	Scrub	Massage	Neutral	Regrowth	,	Log Reductio (Versus Baseline	n e)
Politiciation	Subjects	Baseline (log ₁₀ /hand)	Vol.1	Time ²	Time	-ization 3,4	Below Baseline	Scrub 1/ Day 1	Scrub 2/ Day 2	Scrub 11/ Day 5
1994 TFM	*	•	-	-	-		-	1.0	2.0	3.0
0.75% available I ₂ poloxamer *Jampani <i>et al</i> . 1998	NA	NA	NA	NA	NA	NA	Above Baseline at 6 hr	1.21	1.54	1.79
0.75% PVP-I *Stiles & Sheena 1985	NA	2.08	5 mL	15 sec	NA	Glove	NA	0.38	NA	NA
0.5% PVP-I *Stiles & Sheena 1985	NΛ	2.04	5 mL	15 sec	NA	Glove	NA	0.44	NA	NA
0.3% PVP-I *Stiles & Sheena 1985	NA	2.11	5 mL	15 sec	NA	Glove	NA	0.11	NA	NA
0.1% PVP-I *Stiles & Sheena 1985	NA	2.04	5 mL	15 sec	NA	Glove	NA	0.09	NA	NA
0.01% PVP-I *Stiles & Sheena 1985	NA	2.11	5 mL	15 sec	NA	Glove	NA	0.11	NA	NA

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Table 6: Povidone-Iodine – Surgical Scrub Studies (continued)

Formulation	Test	Resident Flora Baseline	Scrub	Scrub	Massage	Neutral -ization	Regrowth Below		Log Reductio (Versus Baseline	
	Subjects	(log ₁₀ /hand)	Vol. ¹	Time ²	Time	3,4	Baseline	Scrub 1/ Day 1	Scrub 2/ Day 2	Scrub 11/ Day 5
1994 TFM	<u>-</u>		-	-	-	-	-	1.0	2.0	3.0
0.05% stabilized I ₂ *Morrison et al. 1986	10	4.5-4.6 ±0.10-0.12	2 mL	10 sec	5 sec	Glove	NA	0.12	0.12 Week 2/ Wash 2	0.08 Week 3/ Wash 3
PVP-I soln. (Disadine) *Lowbury <i>et al</i> . 1974	NA	NA	gauze applica- tion	~2 min	NA	Glove	Below Baseline at 3 hr	62.3% ±5.9	NA	NA
PVP-I impregnated brush *Paulson, 1994	6	6.57	NA	2 min	1 min	Media	Below Baseline	1.84	2.56	1.52

¹ The indication "5 mL + 5 mL" indicates that an initial volume of test material used to scrub the hands for the time indicated followed by a subsequent addition of test material and scrub.

² The indication "5 min + 5 min" indicates that an initial scrub time was used followed by a subsequent scrub.

³ The term "Media" indicates that the neutralizers were incorporated into the dilution and plating media only.

⁴ The term "Glove" indicates that the neutralizers were incorporated into the sampling fluid in the glove.

^{*} Data not included in the tally tables.

Log reduction values below the 1994 TFM criteria indicated by a shaded box and heavy outline.

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Table 7: Chlorhexidine Gluconate – Preoperative Preparation Studies

	Test	Resident Flora	Scrub	Scrub	Neutral	Log Reduction			Log Red (Versus B	luction aseline) ⁸		
Formulation	Subjects	Baseline (log ₁₀ /site)	Vol.	Time ²	-ization	(Versus Baseline)	10	min	30	min	6 h	ır
		(roginanc)				30 sec	A	\mathbf{G}	A	G	A	G
1994 TFM	-			-	•	1.0	2.0	3.0	-	-	Belo Base	
1%CHG Leyden & Kligman 1981 ^{5,6}	NA	5.78-6.26/cm ²	0.1 mL	NA	NA	NA	5.18 ⁶	NA	NA	NA	Below B	aseline
4% CHG Hibiclens Aly et al. 1998	60	Mean 3.44±0.59 abdomen (Baseline 3 = 3.87±0.62) Mean 5.25±0.57 groin (Baseline 3 = 5.60±0.49)	10 mL	2 min + 2 min	Cup	NA	1.81 (2.24)	2.13 (2.48)	1.79 (1.91)	3.07 (3.42)	Below B	aseline
4% CHG Hibiclens Aly <i>et al</i> . 1998	20	Mean 3.08±0.59 abdomen (Baseline 3 = 3.20±0.82)	10 mL	2 min + 2 min	Cup	NA.	1.98 (2.10)	NA	1.79 (1.91)	NA	Below B	aseline
4% CHG Hibiclens Vorherr <i>et al.</i> 1988	39 perineum 30 groin	5.23 P 4.64 G	50 mL+ ·50 mL	2 min+ 2 min	Cup	NA	4.31P	3.81	NA	NA	Below B	

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Table 7: Chlorhexidine Gluconate – Preoperative Preparation Studies (continued)

Formulation	Test	Resident Flora Baseline	Scrub	Scrub	Neutral	Log Reduction (Versus	10	min	Log Rec	duction laseline)* min		hr
	Subjects	(log ₁₀ /site)	Vol.	Time ²	3,4	Baseline) 30 sec	A	G	A	G	A	G
1994 TFM	***	•	**	**	**	1.0	2.0	3.0		***	Be	low eline
4% CHG Purdue Frederick 1986b	NA	1.0/site	NA	NA	NA	NA	3.415	4.037	3.390	3.953	3.243	3.466
4% CHG Hibiclens Purdue Frederick 1986b	NA	1.0/site	NA	NA	NA	NA NA	3.046	3.472	2.743	3.595	1.624	2.280
4% CHG Hibiclens Stuart Pharmaceuticals 1986	50	NA	NA	NA	NA	NA	2.6418	NA	NA	NA	Below I	Baseline
4% CHG Hibiclens Stuart Pharmaceuticals 1986	50	NA	NA	NA	NA	NA	NA	3.7641	NA	4.1581	N	A
4% CHG Hibiclens Stuart Pharmaceuticals 1986	50	NA	ŊA.	NA	NA	NA	NA	3.6402	NA	3.5635	N	A
4% CHG Hibiclens Stuart Pharmaceuticals 1986	50	NA	NA	NA	NA .	NA	4.9532	NA	NA	NA	Below B	Baseline

Appendix D

Table 7: Chlorhexidine Gluconate – Preoperative Preparation Studies (continued)

	Test	Resident Flora	Scrub	Scrub	Neutral	Log Reduction	-		Log Red (Versus B			
Formulation	Subjects	Baseline (log ₁₀ /site)	Vol.	Time ²	-ization	(Versus Baseline)	10	min	30	min	6	hr
·		(logiosite)			:	30 sec	A	G	A	G	A	G
1994 TFM		••	_	-		1.0	2.0	3.0	*	***	Below Baseline	
4% CHG Hibiclens Stuart Pharmaceuticals 1986	50	NA	NA	NA	NA	NA	2.5322	NA	NA	NA		low eline
4% CHG Hibiclens Stuart Pharmaceuticals 1986	50	NA	NA	NA	NA	NA	NA .	3.4808	NA	3.3298	N	A

- 1 The indication "5 mL + 5 mL" indicates that an initial volume of test material was used to scrub the hands for the time indicated followed by a subsequent addition of test material and scrub.
- 2 The indication "5 min + 5 min" indicates that an initial scrub time was used to scrub the hands followed by a subsequent scrub.
- 3 The term "Media" indicates that the neutralizers were incorporated into the dilution and plating media only.
- 4 The term "Cup" indicates that the neutralizers were incorporated into the sampling fluid in the cup.
- 5 Elaborated flora-skin occluded to increase flora for test-log reductions calculated vs. control site
- 6 Forearm site
- 7 Different authors calculate reductions versus baseline in different manners.
 Log reduction values below the 1994 TFM criteria indicated by a shaded box and heavy outline.

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Table 8: Alcohol – Preoperative Preparation Studies (continued)

Formulation	Test	Resident Flora	Scrub	Scrub	Neutral-	Log Reduction				Reduct us Baseli	
rormuzuon	Subjects	Baseline	Vol. ¹	Time ²	ization 3,4	(Versus Baseline)	10	min	30	min	6 hr
		(log ₁₀ /site)				30 sec	A	G	A	G	A G
1994 TFM	-	_	*	-	-	1.0	2.0	3.0	-	-	Below Baseline
70% IPA SDA/CTFA 1995	NA	3.02	Saturated gauze	1 min	NA	2.25	NA	NA	NA	NA	Below Baseline at 6 hr
70% IPA SDA/CTFA 1995	NA	3.45	Saturated gauze	1 min	NA	2.25	NA	NA	NA	NA	NA.
70% IPA SDA/CTFA 1995	NA	3.66	Saturated gauze	5 min	NA	2.95	NA	NA	NA	NA	NA
70% IPA SDA/CTFA 1995	NA	3.60	Saturated gauze	5 min	NA	2.18	NA	NA	NA	NA	NA
70% IPA Gunderman <i>et al</i> . 1985	NA	NA	NA	NA	Media	1.58	1.58	NA	NA	NA	Below Baseline at 3 and 24 hr
70% IPA Leyden <i>et al</i> . 1996 ^{5,6,7}	10	NA	50μl/ 10 cm²	NA	Media	NA	5.2	NA	NA	NA	Below Baseline
60% IPA Leyden & Kligman 1981 ^{5,6}	NA	5.78-6.26/cm ²	0.1 mL	NA	NA	NA	3.25	NA	NA	NA	Below Baseline
60% IPA Gunderman et al. 1985	NA	NA	NA	NA	Media	1.45	1.35	NA	NA	NA	Below Baseline at 3 and 24 hr
60% n-propanol *Leyden & Kligman 1981 ^{5,6}	NA	5.78-6.26/cm ²	0.1 mL	NA	NA	NA	3.55	NA	NA	NA	Below Baseline

Appendix D Table 8: Alcohol – Preoperative Preparation Studies (continued)

Formulation	Test Subjects	Resident Flora Baseline	Scrub Vol.	Scrub Time²	Neutral- ization 3,4	Log Reduction (Versus Baseline)	10 :	min	(Versu	Reductions Baselin Reductions Baselin Reductions Baselin	6
		(log ₁₀ /site)				30 sec	A	G	Α	G	A G
1994 TFM	•	•	•	-	*	1.0	2.0	3.0	-	-	Below Baseline
70% ethanol Leyden & Kligman 1981 ^{5,6}	NA	5.78-6.26/cm ²	0.1 mL	NA	NA	NA	3.88	NA	NA	NA	Below Baseline
60% ethanol Jampani <i>et al</i> . 2000	14	~4, Groin ~2.7 Abdomen	NA	5 min	Media	NA	2.3	3.12	NA	NA	Below Baseline

The indication "5 mL + 5 mL" indicates that an initial volume of test material was used to scrub the hands for the time indicated followed by a subsequent addition of test material and scrub.

Media

NA

2.77

2.04

NA

NA

Below Baseline

2 The indication "5 min + 5 min" indicates that an initial scrub time was used to scrub the hands followed by a subsequent scrub.

30 sec

- 3 The term "Media" indicates that the neutralizers were incorporated into the recovery media.
- 4 The term "Cup" indicates that the neutralizers were incorporated into the sampling fluid in the cup.

NA

- 5 Elaborated flora-skin occluded to increase flora for test-log reductions calculated vs. control site
- 6 Forearm site

60% ethanol

Jampani et al. 2000

7 Different authors calculate reductions in different manners.

~4, Groin

~2.7 Abdomen

* Not included in the Tally Tables

4

Log reduction values below 1994 TFM criteria indicated by a shaded box and heavy outline.

. Appendix D

Table 9: Povidone-Iodine — Preoperative Preparation Studies

Formulation	Test	Resident Flora	Scrub	· Scrub	Neutral-	Log Reduction		***************************************	Log Re (Versus I	Baseline) ⁸	
rormulation	Subjects	Baseline (log ₁₀ /site)	Vol. ¹	Time ²	ization ^{3, 4}	(Versus Baseline)	10 r			min T	6 hr
						30 sec	Α	G	A	G	A G
1994 TFM			-	•	•	1.0	2.0	3.0	nime.	_	Below Baseline
5% PVP-I Jeng & Severin 1998	12	>5, Groin >3 Abdomen	NA	30 sec	Media	NA	~2.8	~3	~3	~4.3	Below Baseline
7.5% PVP-I Jampani <i>et al.</i> 2000	14	Ab ~2.7/cm ² Groin ≥4/cm ²	NA	5 min	Media	, NA	1.84	1.97	NA	NA	Below Baseline at 4 hr
7.5% PVP-I Arata <i>et al.</i> 1993	14	3.16	NA	NA	Cup	NA	1.17 (unspec- ified time)	NA	NA	NA	NA
10% PVP-I Malathi et al. 1993	. 5	~1.78/cm²	Swab	10 sec	Media	~1.78	NA	NA	NA	NA	NA
10% PVP-I Betadine Vorherr et al. 1988	45 perineum 35 groin	4.91 P 3.99 G	50 mL+ 50 mL	2 min+ 2 min	Cup	NA	3.74P	3.66	NA	NA	Below Baseline at 3 hr
10% PVP-I Gundermann et al. 1985	NA	NA	NA	NA	Media	1.36 (60 sec)	1.06	NA	NA	NA	Below Baseline at 3 and 24
10% PVP-I Betadine Vorherr et al. 1988	47 perineum 44 groin	4.91 P 3.99 G	50 mL+ 50 mL	2 min+ 2 min	Cup	NA	3.65P	3.42	NA	NA	Below Baseline at 3 hr
10%PVP-I Leyden et al. 1996 ^{5,6,7}	10	NA	50μl/ 10 cm ²	NA	Cup	NA	5.36	NA	NA	NA	Below Baseline

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Table 9: Povidone-iodine - Preoperative Preparation Studies (continued)

Formulation	Test	Resident Flora	Scrub	Scrub	Neutral-	Log Reduction				eduction Baseline) ⁸		
roimmation	Subjects	Baseline (log ₁₀ /site)	Vol. ¹	Time ²	ization ^{3,4}	(Versus Baseline)	10 :	nin		min	A C Below Baseline NA Below Baseline Below	hr
The second secon						30 sec	A	G	A	G	A	G
1994 TFM	-		-	**	-	1.0	2.0	3.0	-	-	ł .	
10% PVP-I Betadine Malathi <i>et al.</i> 1993 ⁹	5	<0.70-2.78 (10 control subjects)	Moist swab	10 sec	Cup	98.3%	NA	NA	NA	NA	N	A
PVP-I Betadine Scrub *Leyden & Kligman 1981 ^{5,6}	NA	6-7/cm ²	0.1 mL	NA	NA	NA	2.99	NA	NA	NA		
Betadine *Jeng & Severin 1998	12	>5, Groin >3, Abdomen	NA	5 min	Media	NA	1.2	3.5	2.6	~3.7		low eline
Betadine *Major <i>et al.</i> 1993	10	~1.57 >0-<2	NA	NA	None	~1.52 >0-<2	NA	NA	NA	NA	N.	 A
PVP-I Scrub/PVP-I + ROH *Traore et al. 2000	22	NA	NA	NA	NA	1.5 (30 sec)	2.1 (3 min)	NA	NA	NA NA Bas	Belo Base at 2	line

- The indication "5 mL + 5 mL" indicates that an initial volume of test material was used to scrub the hands for the time indicated followed by a subsequent addition of test material and scrub.
- The indication "5 min + 5 min" indicates that an initial scrub time was used to scrub the hands followed by a subsequent scrub.
- The term "Media" indicates that the neutralizers were incorporated into the dilution and plating media only.
- 4 The term "Cup" indicates that the neutralizers were incorporated into the sampling fluid in the cup.
- 5 Elaborated flora-skin occluded to increase flora for test-log reductions calculated vs. control site
- 6 Forearm site
- 7 Flora transferred from perineum & elaborated by occlusion
- 8 Different authors calculate reductions in different manners.
- 9 Sites tested were on the back.
- P Sampled Perineum
- Data not included in tally tab les.

Log reduction values below the 1994 TFM criteria indicated by a shaded box and heavy outline.

Appendix D Table 9: Povidone-iodine – Preoperative Preparation Studies (continued)

Log reduction values below the 1994 TFM criteria indicated by a shaded box and heavy outline.

Appendix E

Table 1: Triclosan – Healthcare Personnel Handwash Studies

ula-	it cts		S. mar	cescens		Ţ. ē	£%.	0 0	eg de		ca vs.		Log Red Versus I		
Formula- tion	Test Subjects	Base- line (log₁o/ hand)	Vol.	Rub Time	Dry	Wash Vol. ¹	Wash Time ²	Rinse	Massage	Neutrali- zation	Statistical Signif. vs. baseline		Wasl		
	**************************************	m = E	·	***		3				2	D 02 02	1	4	7	10
1994 TFM	-		-	-	. ***	-		**		-	-	2.0		-	3.0
1.5% Triclosan Bartzokas et al., 1987	12	6.66 ± 0.35	5 mL	45 sec	1 min	3 mL + 3 mL	30 sec + 30 sec	30 sec	1 min	Glove	NA	2.91 ± 0.42	3.22 ± 0.41	3.50 ± 0.52	3.78 ± 0.47
1.0% Triclosan Johnson, 1998b	12	NA	5 mL	45 sec	2 min	5 mL	15 sec	30 sec	1 min	Media	NA	1.97	NA	NA	1.89
1.0% Triclosan Jampani et al., 1998 Johnson, 1998 ²	12	9.04	2.5 mL + 2.5 mL	45 sec	2 min	5 mL	30 sec	30 sec	1 min	Media	p<0.05	2.28	NA	NA	2.79

Appendix E

Table 2: PCMX – Healthcare Personnel Handwash Studies

n lä-	it cts		S. mar	cescens		/ol.1	دم.	å	e e	= c	cal vs.			duction ⁶ Baseline)	
Formula- tion	Test Subjects	Base- line (log ₁₀ / hand)	Vol.	Rub	Dry	Wash Vol. ¹	Wash Time²	Rinse Time	Massage Time	Neutrali- zation	Statistical Signif. vs. baseline		Was	h No.	
	,	m – ≅ ≝		<u> </u>	J.F	3		涩	2		ळ छ व	1	4	7	10
1994 TFM	-	-	***	-	-	-	•	•	-	400	Fin	2.0			3.0
1.0% Triclosan Jampani <i>et al.</i> , 1998; Johnson 1998 a	8	8.46 ± 0.28	5 mL	45 sec	Air dry	5 mL	15 sec	30 sec	1 min	Wash1: Media Wash 10: Glove	p<0.05	2.13 ± 0.38	NA	NA	2.14 ± 0.47
1.0% Triclosan Jampani et al., 1998; Johnson, 1998	6	8.46 ± 0.28	5 mL	45 sec	2 min	5 mL	15 sec	30 sec	1 min	Wash1: Media ³ Wash 10: Glove	p<0.05	1.4	NA	NA	1.63
1.0% Triclosan Ciba-Geigy, 1995	12	NA	5 mL	45 sec	2 min	5 mL	15 sec	30 sec	1 min	Glove Wash 10	NA	2.54	2.45 Wash 3	2.61	2.61
1.0% Triclosan Ciba-Geigy, 1990	12	NA	NA	NA	NA	3 mL	30 sec	NA	NA	Glove	NA	~2.54	~3.04	~3.31	~3.72
0.5% Triclosan Johnson, 1998b	12	NA	5 mL	45 sec	2 min	5 mL	15 sec	30 sec	1 min	Media	NA	1.95	NA	NA	1.57
0.5% Triclosan ConvaTec, 1995; Calgon Vestal,1993	30	10.41	NA	NA	1 min	1.5 mL	30 sec	NA	1 min	NA	p=0.05	2.31	2.50 Wash 3	2.57	2.53
0.3% Triclosan Huntington, 1995	6	8.49	5 mL	45 sec	2 min	5 mL	60 sec	30 sec	1 min	Media	NA	1.74	1.98	1.93	1.93

Appendix E

Table 2: PCMX – Healthcare Personnel Handwash Studies

ula-	cts		S. marc	cescens	-	Vol. ¹	£ 2,	Time	e e	÷	cal vs.			duction ⁶ Baseline)	
Formula- tion	Test Subjects	Base- line (log ₁₀ / hand)	Vol.	Rub Time	Dry	Wash \	Wash Time²	Rinse T	Massage Time	Neutrali- zation	Statistical Signif. vs. baseline		Was	h No.	
<u>u_</u>	0)	m = 8 %	>	死亡	PE	3		涩	2	Z	े रहे रहे	1	4	7	10
1994 TFM	*	-	**	45	_		••	-	_	-	**	2.0	-		3.0
0.3% Triclosan Stiles & Sheena, 1987	4	3.88	NA	NA	NA	NA	15 sec	15- 20 sec	NA	Media	NA	2.30	NA	NA	NA
0.3% Triclosan Stiles & Sheena, 1987	4	3.83	NA	NA	NA	NA	15 sec	15- 20 sec	NA	Media	NA	2.39	NA	NA	NA
0.3% Triclosan SDA/CTFA, 1995	NA	NA	NA	NA	NA	NA	30 sec	NA	NA	· · · NA	NA	2.50	2.93 Wash 2	3.05 Wash 3	2.77

Appendix E

Table 2: PCMX – Healthcare Personnel Handwash Studies

ıla-	t		S. mar	cescens		/oi.⁴	£%.	ime	e ge	:	cal vs.		Log Red (Versus	duction ⁶ Baseline)	
Formula- tion	Test Subjects	Base- line (log ₁₀ / hand)	Vol.	Rub	Dry	Wash Vol. ¹	Wash Time²	Rinse Time	Massage Time	Neutrali- zation	Statistical Signif. vs. baseline		Was	h No.	
	0,	8 = 5 %		œË	- =	3		æ			20 SQ P	1	4	7	10
1994 TFM	•	•	**	-	•	-	**	-	-		_	2.0		•	3.0
0.3% Triclosan Gojo, 1999	18	9.0	NA	NA	NA	NA NA	30 sec	NA	NA	NA	NA	2.84	2.93	3.0	3.04
0.3% Triclosan Sheena & Stiles, 1983 ⁵	NA	2.80	NA	5 sec, until dry	5 mL	15 sec	NA	NA	NA	NA	NA	1,32	NA	NA	NA
0.3% Triclosan Sheena & Stiles, 1983 ⁵	NA	3.04	NA	5 sec, until dry	5 mL	15 sec	NA	NA	NA	NA	NA	NA	NA	NA	1.74 Day 3, Wash 6
0.3% Triclosa n Gojo, 1999	18	9.00	NA	NA	NA	NA	30 sec	NA	NA	NA	NA	2.84	2.93 Wash 3	3.00	3.04
0.25% Triclosan Johnson, 1998b	12	NA	5 mL	45 sec	2 min	5 mL	15 sec	30 sec	1 min	Media	NA	1.94	NA	NA	1.75
0.25% Triclosan Sheena & Stiles, 1983 ⁵	NA	2.83	NA	5 sec, until dry	5 mL	15 sec	NA	NA ,	NĄ	NA	NA .	1:23	NA	NA	NA
0.25% Triclosan Sheena & Stiles, 1983 ⁵	NA	2.76	NA	5 sec, until dry	5 mL	15 sec	NA	NA	NA	NA	NA	NA	NA	NA	1.45 Day 3, Wash 6

Appendix E

Table 2: PCMX – Healthcare Personnel Handwash Studies

Formula- tion	st sets	S. mar		marcescens		Vol.¹		Time	e di de	Neutrali- zation 3,4	Statistical Signif. vs. baseline	Log Reduction ⁶ (Versus Baseline)					
form tho	Test Subjects	Base- line (log₁o/ hand)	Vol.	Rub Time	Dry	Wash \	Wash Time²	Rinse	Massage Time	leutra zatio	latist ignif.	Wash No.					
		8 − € €		<u> </u>	L H E	3	Walled Street,	æ	2	Z	ॐ छ व	1	4	7	10		
1994 TFM	***	••	***		**	-	***	470	-		•	2.0	**	-	3.0		
0.25% Triclosan Johnson, 1998b Ciba-Geigy, 1995	12	NA	5 mL	45 sec	2 min	5 mL	15 sec	30 sec	1 min	Glove Wash 10	NA	2.03	1.80 Wash 3	1.95	1.78		
0.1% Triclosan Johnson, 1998b	12	NA	5 mL	45 sec	2 min	5 mL	15 sec	30 sec	1 min	Media	NA	1.67	NA	NA	1.50		
Triclosan *Stepan Company Undated	NA	NA	NA	NA	2 min	NA	NA	NA	NA	NA	NA	~1.2	~1.5 Wash 5	NA	~1.5		
Triclosan *SDA/CTFA, 1995	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	0.82	NA	1.58 Wash 5	1.75		

- The indication "5 mL + 5 mL" indicates that an initial volume of test material was used to scrub the hands for the time indicated followed by a subsequent addition of test material and scrub.
- 2 The indication "5 min + 5 min" indicates that an initial scrub time was used to scrub the hands followed by a subsequent scrub.
- 3 The term "Media" indicates that the neutralizers were incorporated into the dilution and plating media only.
- 4 The term "Glove" indicates that the neutralizers were incorporated into the sampling fluid in the glove.
- 5 E. coli inoculated onto hands through artificially contaminated ground beef.
- Data not included in the Tally Table
- 6 Log reduction values below the 1994 TFM criteria indicated by a shaded box.

Appendix E

Table 2: PCMX – Healthcare Personnel Handwash Studies

-tion	ects	S. marcescens			7-:		Je H	<u>e</u>		<u>6,5 €</u>		Log Red (Versus E	luction ⁶ Baseline	•)	
Formula-tion	Test Subjects	Base- line (log₁o/ hand)	Vol.	Rub Time	Dry Time	Wash Vol. ¹	Wash Time²	Rinse Time	Massage Time	Neutral- ization	Statistical Signif. vs. baseline	Wash No.			
<u>ē</u>	Tes Tes	Ba ii (o)	>	æ≓	PĒ	Ž		IS	N .	2	क छः छ	1	4	7	10
1994 TFM	-	44	-	.			***	-	. ***		-	2.0	-	~	3.0
								<u> </u>						<u> </u>	
3% PCMX Huntington 1995	6	7.630	6 mL	NA	1 min	5 mL	15 sec	NA	1 min'	Glove	NA	2.943	>3.130	>3.130	>3.130
2.5% PCMX Paulson, 1994	5	7.98 ± 0.27	5 mL	1 min	1 min	3 mL	20 sec	30 sec	1 min	Media	p<0.05	1.99 ± 0.12	2.81 ±0.41	3.72 ±0.43	3.99 ± .59
1% PCMX SDA/CTFA 1995	NA	NA	6 mL	NA	NA	5 mL	15 sec	NA	NA	NA	NA	2.39	NA	NA	NA
1% PCMX *SDA/CTFA 1995	NA	NA	6 mL	NA	NA	5 mL	15 sec	NA	NA	NA	NA	NA	2.87 Wash 5	NA	NA
1% PCMX SDA/CTFA 1995	NA	NA	6 mL	NA	NA	5 mL	15 sec	NA	NA	NA	NA	NA	NA	NA	3.06

Appendix E

Table 2: PCMX – Healthcare Personnel Handwash Studies (continued)

tion	ects		S. marce	scens				Time	o		6 S. 21		Log Reduct (Versus Bas		
Formula-tion	t Subjects	Base- line (log ₁₀ / hand)	Vol.	Rub	Dry Time	Wash Vol. ¹	Wash Time ²	Rinse Tir	Massage	Neutral- ization	Statistical Signif. vs. baseline		Was	h No.	
<u>S</u>	Test	83 := 8 gt		₩ E		Š		ig	2	2	क छ व	1	4	7	10
1994 TFM	*	-	-	-	-	-	-	•	- -	-	-	2.0		•	3.0
1% PCMX SDA/CTFA 1995	NA	NA	6 mL	NA	NA	5 mL	15 sec	NA	NA .	NA	NA	NA	NA	NA	0.69 (vs. control soap)
0.6% PCMX Huntington 1995	NA	7.972	5 mL	NA	2 min	1 mL 2 mL 3 mL 4 mL 5 mL	15 sec	NA	1 min	Glove	NA	NA	NA	NA	1.552 1.622 1.469 1.611 1.629
0.6% PCMX Huntington 1995	6	8.613	5 mL	NA	2 min	2 mL	30 sec	NA	1 min	Glove	NA	2.603	2.775	3.050	3.502
0.6% PCMX Johnson Wax Undated	NA	7.58	NA	NA	NA	NA	NA	NA	NA	NA	NA	~1.5	~1.4 Wash 3	~1.7	-1.7
0.6% PCMX Paulson, 1994	5	7.98 ±0.27	5 mL	1 min	1 min	3 mL	20 sec	30 sec	1 min	Media	p<0.05	2.5 ± 0.22	2.73 ±0.04 Wash 3	2.9 ±0.63	2.76 ± 0.27

Appendix E

Table 2: PCMX – Healthcare Personnel Handwash Studies (continued)

tion	ects		S. marce	scens				пе	w	-		Log Reduction ⁶ (Versus Baseline)				
Formula-tion	Test Subjects	Base- line (log ₁₀ / hand)	Vol.	Rub	Dry Time	Wash Vol. ¹	Wash Time ²	Rinse Time	Massage Time	Neutral- ization	Statistical Signif. vs. baseline		Wast	ı No.		
Fo	Tes	Ba = (5) at	>	ŒĒ	OF	×		Ŗ	Σ	Z	S Si St	1	4	7	10	
1994 TFM	•	-	•		-	*	-	•	Andrew Control of the	-	-	2.0	4	•	3.0	
0.6% PCMX Paulson <i>et al.</i> , 1999	5	7.98 ± 0.27	5 mL	NA	1 min	3 mL	20 sec	30 sec	1 min	Media	NA	2.50 ±0.22	2.73 ±0.41	2.91 ±0.63	2.76 ±0.27	
0.53% PCMX SDA/CTFA 1995	NA	NA	NA	NA	NA:	NA	NA	NA	NA	NA	NA	NA	2.69 Wash 5	NA	2.56	
0.5% PCMX SDA/CTFA 1995	NA	NA	NA	NA	NA	NA	30 sec	NA	NA	NA	NA	1,92	2.78 Wash 5	NA	3.21	
0.5%PCMX SDA/CTFA 1995	NA	NA	NA	NA .	NA	NA	30 sec	NA	NA	NA	NA	1.68	1.91 Wash 3	2.26	2.37	
0.5% PCMX Gojo, 1999	18	9.17	NA	NA	NA	NA	30 sec	NA	NA	NA	NA	1.86	2.17 Wash 3	2.42	2.62	
0.325% PCMX Sheena & Stiles, 1983 ⁵	NA	2.70	NA	5 sec	Until dry	5 mL	15 sec	NA	NA	NA	NA	1.40	NA	NA	NA	
0.325% PCMX Sheena & Stiles, 1983 ⁵	NA	2.53	NA	5 sec	Until dry	5 mL	15 sec + 15 sec	NA	NA	NA	NA	NA	1.53	NA	NA	

Appendix E

Table 2: PCMX – Healthcare Personnel Handwash Studies (continued)

Formula-tion	ects	S. marcescens				Time sage		-ie co	cal vs.	Log Reduction ⁶ (Versus Baseline)						
	Subje	Se- le 110/ 1d)	Ä	d e	> e	Wash Vol.	Wash Time ²	Rinse Tir	Massage	Neutral- ization	Statistical Signif. vs. baseline	Wash No.				
	Test	Base- line (log ₁₀ / hand)	Vol.	Rub	Dry	Wa		Rig	S	Z	\ \frac{1}{2} \	1	4	7	10	
1994 TFM		_	. <u>-</u>	-	_	-	-	44		-	-	2.0	· ••		3.0	
							•				1					
0.3% PCMX Gojo, 1999	18	9.22	NA	NA	NA	NA	30 sec	NA	NA .	NA	NA	2.57	2.66 Wash 3	2.69	2.83	
0.3% PCMX SDA/CTFA 1995	NA	NA	NA	NA	NA	NA	30 sec	NA	NA	NA	NA	2.69	2.93 Wash 5	NA	3.46	
0.3% PCMX SDA/CTFA 1995	NA	NA	NA	NA	NA	NA	30 sec	NA	NA	NA	NA	2.40	2.82 Wash 3	2.73	2.31	
PCMX based *Johnson Wax Undated	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	~1.5	NA	NA	NA	

Appendix E

Table 2: PCMX – Healthcare Personnel Handwash Studies (continued)

Formula-tion	ects		-		Time	<u>o</u>		<u> </u>		2.4 ~2.9 NA					
	Test Subjects	9 0 (p		9 P	> e	Wash Vol. ¹	Wash Time²	se Tir	Massage Time	Neutral- ization	Statistical Signif. vs. baseline		Wash	No.	
Forr	Test	Base- line (log ₁₀ / hand)	Vol.	Rub	Dry	Wa		Rinse	Ž	Ž.º	13 Si Si	1	4	7	10
1994 TFM	endo tod Principi di processivano se	<u>~</u>	#8	-	_	-		_		Made .	-	2.0		*	3.0
PCMX *Acute Kare Stuart Pharma- ceuticals, 1986	16	NA	6 mL	NA	1 min	15 sec	NA	NA	NA '	NA	NA	~2.4	~2.9 Wash 5	NA	~3
PCMX impreg-nated brush Hibiclens *Paulson, 1994	36	6.5144	NA	NA	NA	5 mL	30 sec	NA	NA	NA	NA	NA	3.6928 Wash 5	NA	4.3192

¹The indication "2.5 mL + 2.5 mL" indicates that two additions of test material were used to reduce the loss through the subject's fingers.

² The indication "5 min + 5 min" indicates that an initial scrub time was used to scrub the hands followed by a subsequent scrub.

³ The term "Media" indicates that the neutralizers were incorporated into the dilution and plating media only.

⁴ The term "Glove" indicates that the neutralizers were incorporated into the sampling fluid in the glove.

^{5.}E. coli inoculated onto hands through artificially contaminated ground beef.

^{*} Data is not included in the tally tables.

⁶ Log reduction values below the 1994 TFM criteria indicated by a shaded box.